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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,437	01/11/2002	Richard Peregrine Bax	P31167C1	9609

7590

04/10/2003

GLAXOSMITHKLINE

Corporate Intellectual Property - UW2220

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EXAMINER

GOLDBERG, JEROME D

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 04/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

10/043,437

Applicant(s)

BAX ET AL.

Examiner

Jerome D Goldberg

Art Unit

1614

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 January 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 32-49 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 ©and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Rooke et al. patent WO 91/15197, the G.B. 2,005,538H, the Roberto et al., the Feldman et al., the Jacobson et al and the Arguedas et al references, all of record taken together. The Rooke et al. patent teaches a ratio 1:1 to 12:1 with a specific ratio of 8:1 (Example 6, col. 4). The WO 91/15197 teaches a specific ratio of 7:1 (example 2, page 7). The G.B. 2,005,538A, teaches a ratio of 6:1 (note abstract page 1). The Roberto et al. reference discloses the application of the above to children at two times per day for 5 days at 40 mg/kg (see abstract). The Feldman et al. or Jacobson et al reference further teaches the two times per day administration of the claimed antibiotic mixture for children in a 4:1 ratio. The Arguedas et al. reference teaches the combination for treating children with acute otitis media. The reference do not teach the 7:1 ratio for treating bacterial

infection in children and the instant claims are directed to a 7:1 ratio. Accordingly, one skilled in this art would be motivated to employ the 7:1 ratio for treating children in the absence of a side-by-side comparison over the prior art ratio. Applicants' remarks are noted but the Behre et al reference of record states in the Summary, lines 6 and 7 that "there was no statistically significant difference in incidence of adverse experiences between the two groups". The two Groups test were the 4:1 vs. the 7:1 ratio. Moreover, the reference stated as page 166, col. 2, next to last line that "the two regimens showed equivalent clinical efficacy and both were well-tolerated, with a lower incidence of protocol defined diarrhea". Clearly, an Applicants' remarks are insufficient in view of the prior art tests.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner J.D. Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday-Thursday from 9:00 A.M - 3:00 P.M.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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March 24, 2003



JEROME D. GOLDBERG  
PRIMARY EXAMINER